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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/972,035		10/04/2001	Daniel Albert Wettstein	1907.03	1907.03 2866	
26698	7590	07/01/2003				
MYRIAD (	GENETIC	CS INC.	EXAMINER			
LEGAL DEPARTMENT 320 WAKARA WAY				HILL, MY	HILL, MYRON G	
SALT LAK	SALT LAKE CITY, UT 84108			ART UNIT	PAPER NUMBER	
				1648		
				DATE MAILED: 07/01/2003	DATE MAILED: 07/01/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	09/972,035	WETTSTEIN ET AL.					
Office Action Summary	Examiner	Art Unit					
	Myron G. Hill	1648					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
1) Responsive to communication(s) filed on <u>07 M</u>	March 2003 .						
·	is action is non-final.	•					
3) Since this application is in condition for allowa	ance except for formal matters,	prosecution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>							
4) Claim(s) 1-60 is/are pending in the application.							
4a) Of the above claim(s) 24- 43 and 51- 60 is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1- 23 and 44- 50</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers  O∖M The experification is objected to by the Evaminer							
9)⊠ The specification is objected to by the Examiner.  10)□ The drawing(s) filed on is/are: a)□ accepted or b)□ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a)  ☐ The translation of the foreign language provisional application has been received.							
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)	4) Tatonious Summ	ary (PTO-413) Paper No(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6	5) Notice of Informa	ary (PTO-413) Paper No(5)					
O. C. L. L. L. L. L. C.							

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#### **DETAILED ACTION**

Applicant's election with traverse of Group I in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the same searches would be required for all groups and this does not pose a burden on the Examiner. This is not found persuasive because the groups are drawn to different structures, and different methods as stated in the restriction requirement. While the searches may overlap for part of the different groups, they are not coextensive. The groups are distinct for the purposes of examination as noted in the Restriction Requirement.

Applicant is advised that a rejoinder of claims is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 1- 23 and 44- 50 are under consideration in this action. Claims 24-49 and 51- 60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim.

#### Information Disclosure Statement

A signed and initialed copy of IDS paper #6 is enclosed.

### **Priority**

Claim to 60/276,259 is acknowledged.

### Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See at least page 12.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1- 23 and 44- 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "homologue", "derivative", and

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"fragment" are defined in the specification at paragraph spanning pages 11 and 12, page 13 first full paragraph, and page 9 second last paragraph. The first two terms listed are defined relative to a first protein binding to a second protein of the invention. It is not clear from these definitions what the metes and bounds of the proteins are and if they are limited to native proteins or if anything that binds the other protein is a derivative or homologue. It is also noted that the terms are defined only in relation to the first protein of the invention interacting with the second. The term fragment does not require the interaction of the two proteins. From the definitions it is not clear what the proteins are limited to. For the purpose of this action, any protein that binds the first or second protein is considered to meet the meaning of the terms.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1- 8, 12- 15, 17- 20, and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ott.

Ott teaches that an HIV gag p6 protein that binds to a Tsg101 homologue or derivative or fragment. That gag is found in complexes with the ubiquitin as well as covalently bound to it, that there is a specific interaction between the proteins, and that

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gag function and interactions are noted in several other retroviruses (abstract and entire document).

Due to the definition of homologue, derivative, and fragment, ubiquitin meets the limitation of the claimed Tsg101 homologue or derivative or fragment.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9- 11, 16, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ott as applied to claims 1- 8, 12- 15, 17- 20, and 22 above, and further in view of Desai.

Ott teaches protein complexes as discussed above.

Ott does not disclose the full sequence of the peptide sequence binding to gag in Figure 3.

Desai teaches the sequence of gag.

One of ordinary skill in the art at the time of the invention would have been able to determine the missing residue of Ott as well as determine that the gag sequence that

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binds contains the sequence of SEQ ID#s 25 and 31 (positions 452- 461 and 449- 462 of gag, respectively) as taught in Desai.

Thus, it would have been *prima facie* obvious to determine the sequences of Ott using the sequences of Desai with the expectation of success.

Claims 44- 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ott as applied to claims 1- 8, 12- 15, 17- 20, and 22 above, and further in view of Heinrichs.

Ott teaches protein complexes as discussed above.

Ott does not teach expression vectors and fusion proteins of each protein of the complex individually.

One of ordinary skill in the art at the time of the invention would have known that the protein-protein interactions can be studied by many methods including yeast two hybrid systems. Heinrichs et al., 1997 PNAS 94: 115-120 is cited as evidence that one

of ordinary skill would make expression plasmids for both proteins of a pair that form a complex and that these can include fusion proteins.

Thus, it would have been *prima facie* obvious to study the complexes of Ott using the methods of Heinrichs with the expectation of success.

#### Conclusion

No claim is allowed.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Strack and Patniak, from IDS.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill Patent Examiner June 24, 2003

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600